K102589

510(k) Summary

JAN 14 2011

A. Submitter Information

Submitter's name:	Codman & Shurtleff, Inc.
Address:	325 Paramount Drive Raynham, MA 02767
Telephone:	508-880-8349
Fax:	508-828-2777
Contact Person:	Sharon McDermott
Date of Submission:	September 8, 2010

B. Trade/Device Name: CODMAN® BACTISEAL EVD Catheter Set (82-1745 – Ventricular Catheter Component)

CODMAN® HAKIM® BACTISEAL® Ventricular Catheter and Distal Catheter Kit with Bactiseal Shunt System (82-3072 - Ventricular and Distal Catheter Components)

CODMAN® HAKIM® BACTISEAL® Ventricular Catheter with Bactiseal Shunt System (82-3073 - Ventricular Catheter Component)

CODMAN® HAKIM® BACTISEAL® Distal Catheter Kit with Bactiseal Shunt System (82- 3074 – Distal Catheter Component)

Common Name: Ventricular catheter, peritoneal catheter

Classification Name: Central Nervous System Fluid Shunt and Components

Regulatory Class: Class II per 21 CFR § 882.5550

Product Code: JXG

C. Predicate Device: CODMAN® BACTISEAL® Catheter Set (K003322)
CODMAN® BACTISEAL® EVD Catheter Set (K021653)

D. Device Description: The CODMAN® BACTISEAL® Catheter Set and CODMAN® BACTISEAL® EVD Catheter Set are radiopaque catheters packaged with components to facilitate placement and use of the catheters. The catheters are subjected to a treatment process by which the silicone is impregnated with two antimicrobials, rifampicin and clindamycin hydrochloride. Bactiseal silicone catheters have been shown in laboratory studies to reduce the colonization of gram positive bacteria on the tubing surface.

E. Intended Use: Codman® BACTISEAL® EVD Catheter Set is indicated for gaining access to the ventricles of the brain and can be used with dimensionally compatible devices for draining cerebrospinal fluid

(CSF) and other fluids of similar physical characteristics as a means of reducing intracranial pressure and CSF volume.

CODMAN® HAKIM® BACTISEAL® Ventricular Catheter and Distal Catheter Kit with Bactiseal Shunt System is for use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated.

CODMAN® HAKIM® BACTISEAL® Ventricular Catheter with Bactiseal Shunt System is for use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated.

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F. Summary of technological characteristics of the proposed to the predicate device.

The subject of this change is not related to a change to the devices but rather a reduction in the frequency of pyrogen testing; therefore, the technological characteristics of the proposed device are exactly the same as the predicated devices.

G. Performance Data

Control of endotoxin testing has been demonstrated through design and manufacturing controls as demonstrated by the process risk analysis. There were no changes to the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Codman & Shurtleff, Inc.
c/o Ms. Sharon McDermott
Senior Regulatory Affairs Specialist
325 Paramount Drive
Raynham, MA 02767

JAN 14 2011

Re: K102589
Trade/Device Name: CODMAN® BACTISEAL EVD Catheter Set (82-1745 – Ventricular Catheter Component)
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CODMAN® HAKIM® BACTISEAL® Distal Catheter Kit with Bactiseal Shunt System (82- 3074 – Distal Catheter Component)
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: December 15, 2010
Received: December 16, 2010

Dear Ms. McDermott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose, Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102589

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CODMAN® HAKIM® BACTISEAL® Distal Catheter Kit with Bactiseal Shunt System (82- 3074 – Distal Catheter Component)

Indications For Use:

Codman® BACTISEAL® EVD Catheter Set is indicated for gaining access to the ventricles of the brain and can be used with dimensionally compatible devices for draining cerebrospinal fluid (CSF) and other fluids of similar physical characteristics as a means of reducing intracranial pressure and CSF volume.

CODMAN® HAKIM® BACTISEAL® Ventricular Catheter and Distal Catheter Kit with Bactiseal Shunt System is for use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices

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